REMARKS

Applicants respectfully request consideration of the foregoing amendments and the following comments upon continued examination of the present application.

I. Status of the Claims

Claims 25-35 and 76-86 were cancelled previously. Claims 1, 16, 40 and 58 have been amended with exemplary support in the original specification, e.g., at page 22, paragraph [0098]. Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-24, 36-75 and 87-90 will be pending.

II. Rejection of Claims under 35 U.S.C. §103(a)

A. Desai and Stamm

Claims 1-14, 16-24, 40-56, 58-72, 74 and 87-90 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,916,596 to Desai et al. ("Desai") in view of PCT Publication No. WO 98/31360 by Stamm et al. ("Stamm"). Applicants respectfully traverse the rejection.

The claimed invention is directed to nanoparticulate glipizide compositions comprising glipizide particles having an effective average particle size of less than about 2000 nm and at least one surface stabilizer adsorbed on the surface of the glipizide particles. The surface stabilizer is free of intermolecular cross linkages and encompasses conventional surfactants.

In contrast, the active agent of Desai's composition is "encased in a polymeric shell" and the composition is "prepared without the use of conventional surfactant." Desai, column 1, lines 25-30. Desai further discloses that "[t]he polymeric shell is a crosslinked biocompatible polymer" (column 6, lines 4-5) and that "the polymer (*e.g.*, a protein) may be crosslinked as a result of exposure to high shear conditions in a high pressure homogenizer" (column 8, lines 35-

37). More specifically, Desai describes that the protein surface stabilizer is cross-linked via disulfide bond (column 8, lines 54-56). As such, Desai teaches ***away*** from the claimed nanoparticulate glipizide composition which comprises a surface stabilizer free of intermolecular cross-linkages and encompassing conventional surfactants.

Stamm is cited for the alleged teaching of selecting glipizide as an active agent and using glipizide in microparticulate form. However, Stamm fails to compensate for the deficiencies of Desai, i.e., even if one skilled in the art would have selected glipizide as the active agent to obtain a composition described by Desai, such composition would be distinguishable from Applicants' claimed invention, as discussed above.

B. Liversidge and Stamm

Claims 1-8, 10, 11, 13-15, 17-24, 40-43, 45-50, 52, 53, 55-65, 67, 68, 70-75 and 87-90 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,145,684 to Liversidge et al. ("Liversidge") in view of Stamm. Applicants respectfully traverse the rejection.

As submitted in the response filed on July 13, 2009, the combined teachings of Liversidge and Stamm fail to render Applicants' claimed invention obvious because one skilled in the art would not have had any reason to select the active agent of the claimed invention, glipizide, and because a reasonable expectation of successfully obtaining a stable nanoparticulate glipizide composition is lacking. The arguments submitted in the prior response are incorporated by reference.

The Examiner is silent concerning Applicants' argument of lack of a reasonable expectation of success. As to a reason to select glipizide as the active agent, the Examiner asserts that Applicants attacked the cited references individually in the prior response. *See* final Office Action, page 7, first paragraph. Applicants respectfully disagree.

The primary reference, Liversidge, disclose a laundry list of over 40 categories of drugs without any teaching or suggestion of selecting an anti-diabetic agent, such as glipizide, as the active agent. Rather, Liversidge teaches anti-cancer drugs and steroids in preferred embodiments. Similarly, Stamm lists numerous poorly soluble active agents without any explicit teaching to select glipizide. Accordingly, even when the cited references are combined, one skilled in the art would not have gleaned from the cited art that glipizide is a desirable active agent for the nanoparticulate composition.

C. Desai or Liversidge, Stamm, and Baralle

Claim 16 is rejected under 35 U.S.C. §103(a) for allegedly being obvious over Desai or Liversidge, in view of Stamm and GB 2316316 to Baralle et al. ("Baralle"). Applicants respectfully traverse the rejection.

Desai, Liversidge and Stamm are discussed in the foregoing sections. Baralle is cited for the alleged teaching of "a bimodal particle distribution" (final Office Action, page 5, last paragraph). Because Baralle fails to remedy the deficiencies of Desai, Liversidge and Stamm, claim 16 is non-obvious for depending from a non-obvious base claim.

D. Desai or Liversidge, Stamm and Lo

Claims 36-39 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Desai or Liversidge, in view of Stamm and U.S. Patent No. 4,389,397 to Lo et al. ("Lo"). Applicants respectfully traverse the rejection.

Desai, Liversidge and Stamm are discussed in the foregoing sections. Lo is cited for the alleged teaching of a low viscosity formulation (final Office Action, page 6, last paragraph). Lo fails to address the deficiencies of Desai, Liversidge and Stamm. For this reason alone, claims 36-39 are non-obvious over the cited art.

Additionally, Lo solves the poor solubility problem of avermectin compounds by forming micelles. *See* the abstract. More specifically, the active agent is ***dissolved*** in surfactants, and then stabilized by certain cosolvents. One skilled in the art would not have any reason to conclude that Lo's composition having a certain viscosity would have any suggestion regarding the viscosity of the claimed invention. This is because the claimed invention employs an entirely differently technology than that of Lo, and the active agent of the claimed invention exists in ***solid particles***, rather than in a ***dissolved*** state.

In view of the foregoing, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. §103(a).

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: June 2, 2010

By _____

FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717